

respectfully requested. Initially, the claims have been amended to improve their readability and clarity. Also claims 19-24 have been added which are directed towards treating a disease or condition which results from excess free radicals. Claim 25 has been added and directed toward the use of the composition for short term detoxification. Claims 26 to 29 have been added and directed to the composition including a probiotic, healthy bacteria, L-glutamine and N-acetyl-D-glucosamine, respectively, which were previously set forth generally in claims 2 and 3.

Claims 6-18 have been rejected as failing to set forth steps in a process. Applicants disagree. The claims are directed towards a method of treating a particular disease or condition. The step involved is the systematic administration of a compound to treat a specified disease or condition. The mere fact that the treatment is cited in one step does not make it any less a method.

As to the use of the acronyms in claim 9, they are defined in the specification at pages 18-19. As to the Examiner's rejection of claims 9-14, Applicants also disagree as to the enablement of these claims. The claims are directed toward providing a treatment of a specific condition. As supported by articles recited in the specification, the levels of NAC (and glutathione) has certain effects to address a particular condition.

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The present invention provides a vehicle to provide for the absorption of NAC across the cellular membrane which, in turn, provides the intended result. A skilled worker would not have difficulty in implementing the invention to address a particular situation.

The use of the compound as set forth in the specification and claims would teach a user as to the proposed use of the compound. For example, from the article entitled "In Vitro Glutathione Supplementation Enhances Interleukin-2 Production and Mitogenic...", Dayong Wu, et al. cited in the specification, it speaks of the effect of glutathione in affecting T-cell levels. The present invention provides a vehicle to allow for the absorption of NAC across the cellular membrane which would then affect T-cell levels according to the article.

Claims 15 and 16 were amended to correct the omitted word.

Turning now to the merits, the claims have been rejected as either anticipated or obvious in view of BIODYNAMAX, BioDynamax Supplement - Ultra Antioxidants Tablets, Product Alert (22 Dec., 1997). While it is true that BIODYNAMAX discloses N-acetylcysteine in an admixture with Vitamin C, milk thistle (sylimarin), quercitin and alpha-lipoic acid, there are several reasons why this reference does not anticipate the subject invention.

Firstly, BIODYNAMAX is stated to be an antioxidant (it states it is a combination of "21 antioxidants"). Therefore, in the absence of any evidence to the contrary, it should be assumed that all constituents in the BIODYNAMAX admixture are intended as antioxidants.¹

The subject invention, on the other hand, is a formulation intended to raise the intracellular levels of glutathione ("GSH") in mammalian cells. The manner in which this is accomplished is by one of facilitation. The inventors have investigated all the limiting factors in GSH production and have attempted to remedy these limiting factors in a purposeful and systematic manner.

Vitamin C is provided because it is a substance which, when present in sufficient quantities (i.e., at least 1000 mg or greater) facilitates the transport of NAC across the cell membrane, thus making NAC available for GSH production. Claim 1 has been amended to specifically include this limitation and all of the claims present depend from claim 1.

Vitamin C is a common antioxidant, and is provided in the BIODYNAMAX admixture for that purpose. But in the present invention, the purpose and effect of providing this nutrient is very different. It is submitted that the usual dose of vitamin C provided when use is intended

¹ Note, Applicants' attorney has attempted to locate further information on this product through searches on Internet using Metacrawler and Google, Hoover's site, Dialog and D&B file but was unable to obtain anything regarding the concentrate of each

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as an antioxidant is 500 mg. The present invention provides that a minimum of 1000 mg. shall be used. This higher dose is required precisely because the dose requirements are different when vitamin C is taken as a facilitator of NAC absorption, as opposed to being taken as an antioxidant.

In general, there are four limiting factors in GSH production which this admixture is intended to overcome are: 1) providing the essential elements necessary for GSH production; 2) improving gastro-intestinal health the improve absorption of these essential elements; 3) improving liver function, being the organ where a much of mammalian GSH production occurs; and, 4) improving recycling of GSH and the enzymatic reactions that promote GSH production.

With respect to the first factor, a major limiting factor in intracellular GSH production is the availability of the nutrients and precursors needed to synthesize GSH. GSH is produced in the mammalian cell in the gamma-glutamyl cycle, where cysteine is identified as the rate-limiting factor. N-acetylcysteine ("NAC") is an efficient source of cysteine, and is provided for that reason.

With respect to the second factor, gastro-intestinal function, this factor is intended to increase the absorption of the necessary nutrients and precursors into

constituent.

present invention is much more specific and is keyed to liver health for the purpose of promoting GSH production and maintaining GSH levels.

Lastly, the invention includes milk whey as a source of dietary protein. This ingredient is included to optimize the function of the other elements of this invention, by supplying a source of nutrients which is considered advantageous.

The product is not a mere collection of antioxidants, as in the BIODYNAMAX reference and it is submitted that absence of evidence to the contrary that the levels of vitamin C in the BIODYNAMAX admixture are no more than 500 mg., which is the usual dose employed in a vitamin which employs Vitamin C as an antioxidant alone but which is not sufficient to facilitate the absorption of NAC across the cellular membrane. This is contrasted with the minimum dose of 1000 mg. suggested by one preferred embodiment of the subject invention. Another preferred embodiment suggests a dose between 5,000 to 50,000 mg.

Turning briefly to the reference to KAMINSKI, et.al. which is cited in combination with BIODYNAMAX, KAMINSKI discloses that some of the compounds noted therein will promote GI-tract and liver health by removing oxidative stress and pathogens from the patient's system. KAMINSKI teaches that intestinal inflammation leads directly to the production of tumor necrosis factor - alpha (TNF-a),

and offers treatments which will tend to help the immunocompromized gut stave off assaults which lead to inflammation. Pathogens and oxidative stress are the main concerns in this regard, and KAMINSKI employs L-glutamine and probiotics to help in this regard.

Therefore, KAMINSKI teaches that L-glutamine and probiotics help by alleviating the effects of oxidative stress and infection due to pathogens. There is no basis to combine the teachings of BIODYNAMAX and KAMINSKI because L-glutamine and probiotics, while useful to combat the effects of oxidative stress, they are not antioxidants as such. BIODYNAMAX is a composition made up only of antioxidants, and thus would not include these two additional compounds.

Moreover, the present invention teaches that L-glutamine and probiotics are taken to improve the function of the GI tract with the primary goal of absorbing the nutrients necessary to the intracellular production of GSH, primarily NAC. This teaches away from KAMINSKI, which teaches that improved GI tract function helps to avoid the intake of pathogens and oxidative toxins.

Similarly, neither BIODYNAMAX nor KAMINSKI teach that N-acetyl-d-glucosamine will further the goal of absorbing nutrients necessary to the intracellular production of GSH.

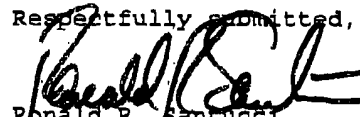
As to the reference to Bounous, it merely concerns

the use of milk whey as a source of dietary protein. As such, there is nothing in the reference which would correct the uncombinability of Kaminski with BIODYNAMAX nor insufficiency of the BIODYNAMAX itself.

Accordingly, it is submitted that the claims as presented are in condition for allowance, a notice of which is earnestly solicited.

The Commissioner is authorized to charge any additional fees that may be required to Deposit Account No. 501145, Order No. 4250-2.

Respectfully submitted,


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